BIOPLATE®

K012908

NOV 2 8 2001

510(k) Summary
The Bioplate® Resorbable Bone Screw

August 28, 2001

Bioplate, Inc.
6911 Melrose Avenue
Los Angeles, CA 90038
Tel: (323) 549-9500, Fax: (323) 935-0110

Contact: Eric V. Hohenstein

PROPRIETARY NAME

Bioplate® Resorbable Bone Screw

COMMON NAME

Absorbable Bone Screw

CLASSIFICATION NAME

Screw, fixation, bone

CLASSIFICATION NO

87HWC

DEVICE CLASSIFICATION

Class II, 21 CFR 888.3040

STATEMENT OF SUBSTANTIAL EQUIVALENCE

The Bioplate® Resorbable Bone Screws are substantially equivalent to the screws of the Bioplate® Bone Plating System for Craniomaxillofacial Surgery, Biolactate™,based on the subject devices' similarity to the predicate devices in intended use, design, material, and principles of operation.

DESCRIPTION OF DEVICE

The Bioplate® Resorbable Bone Screws are resorbable implants made from a Poly(L-lactide) copolymer. The screws are provided pre-sterilized by gamma radiation and are not intended to be resterilized by the user.

INDICATIONS FOR USE:

Bioplate® Resorbable Bone Screws are intended for use in conjunction with Codman Craniosorb™ plates and meshes in the treatment of fractures and reconstructive procedures of the craniomaxillofacial skeleton in which resorbable fixation is desired. The plates and screws are used to align and stabilize fractures of bony tissue while normal tissue healing occurs.

The Bioplate® Resorbable Bone Screws are intended for minimally load bearing fixation for the following indications:

- Reconstructive procedures of the craniomaxillofacial skeleton
- Repair of Craniofacial fractures
- Cranial bone fixation
- Brow lift procedures

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 8 2001

Mr. Eric Hohenstein
Bioplate, Incorporated
6911 Melrose Avenue
Los Angeles, California 90038

Re: K012908
Trade/Device Name: Bioplate Resorbable Bone Screw
Regulation Number: 872.4880 and 872.4760
Regulation Name: Resorbable Bone Screw
Regulatory Class: II
Product Code: DZL and JEY
Dated: August 28, 2001
Received: August 30, 2001

Dear Mr. Hohenstein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012908

STATEMENT OF INDICATIONS FOR USE

DEVICE NAME:

The Bioplate Resorbable Bone Screw

INDICATIONS FOR USE:

Bioplate Resorbable Bone Screws are intended for use in conjunction with Codman CRANIOSORB™ plates and meshes in the treatment of fractures and reconstructive procedures of the craniomaxillofacial skeleton in which resorbable fixation is desired. The plates and screws are used to align and stabilize fractures of bony tissue while normal tissue healing occurs.

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRANCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109 (Optimal Format 1-2-96)

Susan Runner
Division Sign-Off

510(k) Number K012908